

# PATENT COOPERATION TREATY

From the:  
INTERNATIONAL SEARCHING AUTHORITY

CORRECTED VERSION

To:

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**PCT**

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

|  |  |  |             |
|--|--|--|-------------|
|  |  | Date of mailing<br>(day/month/year)            | 25 OCT 2004 |
| Applicant's or agent's file reference<br>501792 TVG  |  | FOR FURTHER ACTION<br>See paragraph 2 below    |             |
| International application No.<br>PCT/NZ2004/000153   | International filing date (day/month/year)<br>19 July 2004 | Priority date (day/month/year)<br>18 July 2003 |             |
| International Patent Classification (IPC) or both national classification and IPC<br>Int. Cl. 7 A61K 35/74, A61P 31/04 |  |  |             |
| Applicant<br>BLIS TECHNOLOGIES LIMITED et al   |  |  |             |

1. This opinion contains indications relating to the following items:

|                                     |              |  |
|-------------------------------------|--------------|--|
| <input checked="" type="checkbox"/> | Box No. I    | Basis of the opinion   |
| <input type="checkbox"/>            | Box No. II   | Priority   |
| <input type="checkbox"/>            | Box No. III  | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability   |
| <input type="checkbox"/>            | Box No. IV   | Lack of unity of invention   |
| <input checked="" type="checkbox"/> | Box No. V    | Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| <input checked="" type="checkbox"/> | Box No. VI   | Certain documents cited  |
| <input type="checkbox"/>            | Box No. VII  | Certain defects in the international application   |
| <input type="checkbox"/>            | Box No. VIII | Certain observations on the international application  |

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

|   |   |
|---|---|
| Name and mailing address of the IPEA/AU<br><b>AUSTRALIAN PATENT OFFICE</b><br>PO BOX 200, WODEN ACT 2606, AUSTRALIA<br>E-mail address: <a href="mailto:pct@ipaaustralia.gov.au">pct@ipaaustralia.gov.au</a><br>Facsimile No. (02) 6285 3929 | Authorized Officer<br><b>M. ONG</b><br>Telephone No. (02) 6283 2491 |
|---|---|

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/NZ2004/000153

**Box No. I Basis of the opinion**

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.  
 This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
  - a. type of material  
 a sequence listing  
 table(s) related to the sequence listing
  - b. format of material  
 in written format  
 in computer readable form
  - c. time of filing/furnishing  
 contained in the international application as filed.  
 filed together with the international application in computer readable form.  
 furnished subsequently to this Authority for the purposes of search.
3.  In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/NZ2004/000153

**Box No. V** **Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

**1. Statement**

|                               |             |     |
|-------------------------------|-------------|-----|
| Novelty (N)                   | Claims 1-70 | YES |
|                               | Claims      | NO  |
| Inventive step (IS)           | Claims 1-70 | YES |
|                               | Claims      | NO  |
| Industrial applicability (IA) | Claims 1-70 | YES |
|                               | Claims      | NO  |

**2. Citations and explanations:**

The following document identified in the International Search Report has been considered for the purposes of this report:

D1: WO 2003/0070919

Novelty (N):Claims 1-70

The invention is directed to the inhibition of halitosis causing anaerobic bacteria (eg. black pigmented *Prevotella*, *Eubacterium* and *Micromonas* sp) in the oral cavity by the introduction of a BLIS-producing *S. salivarius* or an extract thereof.

The document cited in the ISR were category A only. Therefore the subject matter of the present claims is not disclosed in any of the patent document cited. Hence the requirements of Article 33(2) PCT with regard to the requirement for novelty.

D1 was published after the priority date and will not be considered further. See however the indication in Box VI.

Inventive Step (IS):Claims 1-70

Claims 1-70 meet the criteria set out in PCT Article 33(3) with regard to the requirement of Inventive Step because the prior art does not obviously suggest to a person skilled in the art to use a BLIS-producing *S. salivarius* or an extract thereof to inhibit halitosis.

Industrial Applicability: Claims 1-70

Claims 1-70 have industrial applicability

**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

**PCT/NZ2004/000153**

**Box No. VI      Certain documents cited**

**1. Certain published documents (Rules 43bis.1 and 70.10)**

| Application No.<br>Patent No. | Publication date<br>( <i>day/month/year</i> ) | Filing date<br>( <i>day/month/year</i> ) | Priority date (valid claim)<br>( <i>day/month/year</i> ) |
|-------------------------------|---|--|--|
| WO 2003/070919                | 28/08/03                                      | 21/02/03                                 | 22/02/02   |

The document disclose the essential features of claims 1-70, in that the inhibition of halitosis is treated by the introduction of a BLIS-producing *S. salivarius* or an extract thereof in the oral cavity.

With regard to the document(s) listed in Box VI under "certain documents cited", these are documents published prior to the international filing date but later than the priority date claimed but which would otherwise be considered to be of particular relevance.

Under the PCT, novelty is considered only in respect of documents published before the priority date. The relevance of a document published after the priority date is dependent upon national law. Such documents are excluded from consideration in preliminary examination, under the PCT Guidelines but have been included here for information.

**2. Non-written disclosures (Rules 43bis.1 and 70.9)**

| Kind of non-written disclosure | Date of non-written disclosure<br>( <i>day/month/year</i> ) | Date of written disclosure<br>referring to non-written disclosure<br>( <i>day/month/year</i> ) |
|--------------------------------|---|--|
|                                |   |  |